IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Arnold P. Nerenberg

Examiner: McIntosh III, Traviss C.

Serial No.: 10/748,615

Group Art Unit: 1623

Filed: 12/30/2003

Docket No.: **NERE-3815**

Title: **NUTRITIONAL SUPPLEMENT FOR ENHANCING THE PRODUCTION AND EFFECT OF NATURAL HUMAN GROWTH HORMONE**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant requests review of the final rejection of claims 1-57 under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the enablement requirement.

Applicant cites the following requirements for enablement in MPEP § 2164.04:

> "A specification disclosure which contains a teaching of the manner and process of **making and using** an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.... As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement..."" (emphasis added) .

Applicant's specification, page 10, col. 3 - page 13, line 5 "contains a teaching of the

manner and process of **making and using** an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented" (emphasis added).

. Making the invention is enabled, because: the specification teaches how to obtain the claimed ingredients; and the specification teaches structural forms into which the ingredients of the claimed nutritional supplement are assembled.

The specification, page 10, lines 3-5 describes how to obtain the claimed ingredients ("Each ingredient of the nutritional supplement of the present invention may be prepared in accordance with any method known to one of ordinary skill in the art. Alternatively, each ingredient may be obtained in a fully prepared from a commercially available source.") Since each claimed ingredient may be obtained from a commercially available source, there cannot be lack of enablement with respect to obtaining the claimed ingredients.

The specification, page 10, lines 6-8 describes structural forms into which the ingredients of the claimed nutritional supplement are assembled ("The nutritional supplement of the present invention may be in any of the following structural forms: a chewable form, a liquid form, a spray form, a capsule form, a suppository form, and a powder form, as described next in conjunction with FIGS. 1-5."). The specification, page 10, line 9 - page 12, line 17 and FIGS. 1-5 provides a detailed description of each structural form of the claimed nutritional supplement.

Using the invention is enabled in the specification, page 12, line 18 - page 13, line 5, which recites: "The nutritional supplement of the present invention may be ingested on a regular basis, such as a daily intake at a dosage tailored to an individual's needs; i.e., the nutritional supplement is to be taken regularly as multiples (1X, 2X, etc.) of the structural units (pills, tablets, capsules, etc.) in accordance with the needs of the individual. For example, a young person engaged in regular strenuous exercise (e.g., a weight lifter) is likely to need higher daily

doses than does a senior citizen leading a sedentary life. Alternatively, the nutritional supplement of the present invention may be ingested on an as-needed basis at a dosage tailored to the individual's needs. Medical or nutritional counseling may be beneficial for arriving at a desirable or optimal dosage tailored to the individual's needs."

Since Applicant's specification "contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented", MPEP § 2164.04 states that the "specification disclosure ... must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support". Applicant's note that the office action has not indicated that "there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support". Moreover, the office action has not complied with the following requirement in MPEP § 2164.04: "As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement...."" Applicant reiterates that the Examiner has not challenged "the objective truth of the statements contained therein which must be relied on for enabling support".

Based on the preceding analysis, MPEP § 2164.04 requires that the "specification disclosure ... **must** be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph" (emphasis added) .

Applicant cites MPEP § 2164.01 which states the enablement requirement as follows: "Any analysis of whether a particular claim is supported by the disclosure in an application

requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to **make and use** the claimed invention" (emphasis added).

As explained *supra*, Applicants respectfully contend that Applicant's specification "when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention:.

The Examiner alleges: "the instant disclosure is not seen to be sufficient to enable one to make or use the combination of the claimed agents without undue experimentation. It is noted that the specification should teach how to **make and use** the invention, not teach how to figure out for oneself how to make and use the invention" (emphasis added). In response, Applicant has cited the specific content in the specification that teaches how to **make and use** the invention.

The Examiner's basis for alleging undue experimentation is based on the Examiner's allegation that the specification does not include the following items:

(1) test data reflecting use of the claimed nutritional supplements on subjects;

(2) an indication of toxicity of the claimed nutritional supplements; and

(3) an indication of therapeutic index for the claimed nutritional supplements.

In response, Applicant respectfully contends that none of the preceding items (1)-(3) are required by the MPEP or by case law to be present in the specification to enable one skilled in the pertinent art to make and use the claimed nutritional composition Applicant respectfully suggests that the Examiner has arrived at the preceding list of requirements on the basis of the Examiner's intuition without any legal support, because the Examiner has not presented evidence

from the MPEP, case law, or other credible legal authority to demonstrate that the preceding items (1)-(3) are required to overcome an allegation of undue experimentation. In the absence of such evidence, Applicant respectfully contends that the Examiner's arguments are not legally persuasive and cannot be used to reject claims 1-57 for alleged lack of enablement.

Additionally, Applicant asserts that the specification, page 4, lines 2-16 cites test results of a relevant study pertaining to combining L-arginine-2-pyrrolidone-5-carboxylate and L-lysine hydrochloride. The specification, page 4, line 17 - page 5, line 12 discusses the benefit provided by the present invention of adding cortisol to the combination of L-arginine-2-pyrrolidone-5-carboxylate and L-lysine hydrochloride. The specification also describes benefit provided by each additional ingredient that may be used in the claimed nutritional supplement. Furthermore, the specification describes the role of the ingredients in promoting beneficial use of the claimed nutritional supplement with respect to muscular benefit in conjunction with physical exercise, emotional stress, physical illness, etc. (e.g., see specification, page 4, line 17 - page 5, line 3).

Based on the preceding arguments, Applicant respectfully contends that claims 1-57 do not fail to comply with the enablement requirement under 35 U.S.C. § 112, first paragraph. Accordingly, Applicant respectfully requests that the rejection of claims 1-57 under 35 U.S.C. § 112, first paragraph be withdrawn.

The Director is hereby authorized to charge and/or credit Deposit Account 19-0513.

Date: 03/19/2007

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